Clinical and laboratory adverse effects associated with long-term, low-dose isotretinoin: incidence and risk factors. The Isotretinoin-Basal Cell Carcinomas Study Group

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Abstract: Adverse effects associated with the long-term low-dose regimens of retinoids used in cancer chemoprevention studies are not well described. In order to examine the clinical and laboratory adverse effects of 3 years of intervention with isotretinoin (10 mg/day) and to assess potential risk factors for developing these, we collected adverse effect data on patients participating in a randomized, placebo-controlled trial designed to evaluate the effectiveness of isotretinoin in preventing the subsequent occurrence of new basal cell carcinoma. Our results showed a significantly higher incidence of adverse mucocutaneous effects and serum triglyceride elevations in the isotretinoin group ($P < 0.001$). Associated risk factors included male gender, very fair skin, and elevated pretreatment triglyceride levels. The toxicity observed, although less severe and less frequent, was similar to that seen with higher doses and should be weighed with adverse skeletal effects when considering long-term treatment of patients with moderate cancer risk.